

AUG 19 1999

K992506



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510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

Date:

July 23, 1999

Name of Submitter:

OEC Medical Systems, Inc.
384 Wright Brothers Drive
Salt Lake City, UT 84116
801-328-9300

Corresponding Official:

Ted L. Parrot,
Vice President, Quality Assurance & Regulatory Affairs.

Device Proprietary Name:

MINI 6800 Digital Mobile C-arm

Classification Name:

Mobile X-ray System

Common/Usual Names:

Mini C-arm
Mobile C-arm

Substantial Equivalence:

The MINI 6800 Digital Mobile C-arm is substantially equivalent to the following devices that are currently marketed:

- MINI 6600 Digital Mobile C-arm
- FluoroScan Premier
- ORCA Orthopedic C-arm

All of these devices are mobile C-arm type diagnostic x-ray systems intended for fluoroscopic imaging, particularly during orthopedic procedures and extremity examinations. All systems include a high-voltage x-ray generator, stationary anode x-ray tube, image intensifier, video image display, digital image processing and image storage capability.

Device Description:**Indications for Use**

The MINI 6800 Digital Mobile C-arm is designed to provide the physician with general fluoroscopic visualization of the patient including but not limited to surgical orthopedic and extremity imaging. The device is not intended for whole-body pediatric imaging.

User Characteristics

The device is used by health care professionals such as medical doctors, surgeons, radiologists and technologists in a hospital or clinical environment. In addition to being qualified within their respective medical fields, users must be trained in the use of medical x-ray equipment. OEC applications specialists train the user in the proper use of this product. The device labeling stipulates that only properly trained persons operate this equipment.

General Description

The OEC mobile workstation, which supports image display monitors, image processing and recording devices, is combined with a miniature C-arm to create the MINI 6800 Digital Mobile C-arm.

Interfaces are provided for optional peripheral devices such as thermal or laser printers and VCRs. Video outputs are compatible with RS-170 format for North American markets, CCIR format for international markets, and DICOM 3.0.

The MINI 6800 has the following physical characteristics:

- All components are contained in one mobile workstation.
- An articulating arm is attached to the workstation and extends out from the main cabinet to position the x-ray imaging components.
- All mechanical positioning of the workstation and articulating arm is manual (non-motorized).
- The system is powered by a non-detachable power cord.
- Power ratings between 100–240 VAC, 4–6 Amps at 50/60 Hz.
- Internal system power is insulated from input power by an isolation transformer.
- Fluoroscopic operation:

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- 40 to 80 kVp
- 20 to 160 μ A (0.020 to 0.160 mA)
- Automatic Exposure Rate Control

Major components of the system include:

- Dual video monitors
- Input isolation transformer
- Digital image processing and x-ray control
- Monoblock X-ray tube and high-voltage power supply
- Image intensifier

Standards:

The MINI 6800 Digital Mobile C-arm is designed in accordance with product safety requirements established in the following standards:

21 CFR 1020.30-32	Federal Performance Standard for Diagnostic X-ray Systems
ANSI/NFPA 70 & 99	National Electrical Code and Standard for Health Care Facilities
UL 2601	Medical Electrical Equipment
CSA-C22.2 No. 601.1-M90	Medical Electrical Equipment
IEC 60601-1	Medical Electrical Equipment, General Requirements for Safety
IEC 60601-1-2	Medical Electrical Equipment, Electromagnetic Compatibility
IEC 60601-1-3	Medical Electrical Equipment, Radiation Protection in Diagnostic X-ray
IEC 60601-1-4	Medical Electrical Equipment, Programmable Electrical Medical Systems
IEC 60601-2-7	Medical Electrical Equipment, Safety of HV/X-ray Generators
IEC 60601-2-28	Medical Electrical Equipment, X-ray Tubes and X-ray Source Assemblies
IEC 60601-2-32	Medical Electrical Equipment, Safety of Associated X-ray Equipment
93/42/EEC - Annex 1	Essential Requirements of the Medical Devices Directive

This concludes this 510(k) Summary.



Ted L. Parrot,
Vice President, Quality Assurance & Regulatory Affairs
OEC Medical Systems, Inc.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Ted L. Parrot
Vice President, Quality Assurance & Regulatory Affairs
OEC Medical Systems, Inc.
384 Wright Brothers Drive
Salt Lake City, Utah 84116

Re: K992506
Mini 6800 Digital Mobile C-Arm
Dated: July 23, 1999
Received: July 27, 1999
Regulatory Class: II
21 CFR 892.1720/procode: 90 IZL

Dear Mr. Parrot:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

CAPT Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use Statement

Applicant: OEC Medical Systems, Inc.

510(k) No. (if known):

Device name: MINI 6800 Digital Mobile C-arm

Indications for use: The MINI 6800 Digital Mobile C-arm is designed to provide the physician with general fluoroscopic visualization of the patient including but not limited to surgical orthopedic and extremity imaging. The device is not intended for whole-body pediatric imaging.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH Office of Device Evaluation (ODE)

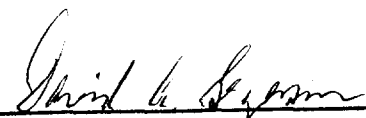
Prescription Use ☒

OR

Over-The-Counter

(Per 21 CFR 801.109)

(Optional Format 1-2-96)


(Division Sign-Off)Division of Reproductive, Abdominal, ENT,
and Radiological Devices

510(k) Number

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